UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,290	01/11/2007	Robert Edward Coleman	33540-US-PCT	2763

1095 7590 01/06/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
01/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,290	COLEMAN ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,11-13,26 and 28* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,11,26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on September 23, 2008.

Status of Claims

Amendment of claim 26, and cancellation of claims 1, 5-6 and 27 is acknowledged.

Claims 7, 11-13, 26 and 28 are currently pending and are the subject of this office action.

Claims 12 and 13 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 25, 2008

Claims 7, 11, 26 and 28 are presently under examination.

Priority

The present application is a 371 of PCT/EP04/13728 filed on 12/02/2004, and claims priority to foreign application: UNITED KINGDOM No. 0328040 filed on 08/04/2003.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or

Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (Maintained Rejection)

Claims 7, 11, 26 and 28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jagdev et. al. (British Journal of Cancer (2001) 84:1126-1134).

The reasons for this rejection have been provided in the previous office action dated March 24, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that Jagdev et. al., in an example on page 1130, disclose that the administration of zoledronic acid and paclitaxel together caused a two-fold increase in the proportion of apoptotic MFC-7 cells when compared with either drug alone. By contrast, the present application shows that when zoledronic acid is administered after paclitaxel, a ten-fold increase or a forty fold increase in induction of apoptosis.

Examiner's response: Jagdev et. al. actually teach that combining zoledronic acid and paclitaxel caused a greater than 2-fold increase in the proportion of apoptotic MCF-7 cells when compared with either drug alone. The fluorescence DNA labeling assay revealed that treatment with 10 micromolar zoledronic acid and 2 nanomolar paclitaxel resulted in a 5-fold increase in apoptosis compared with zoledronic acid alone

and a 4-fold increase compared with paclitaxel alone (see page 1130, left column). They also provide isobolograms for different concentration combinations of both drugs.(see page 1131). Applicant only provides data for a couple of concentrations of the combined drugs: 25 micromolar of zoledronic acid and 2 nanomolar of paclitaxel (see experiment 1 on page 15) and 1 micromolar zoledronic acid and 2 nanomolar of paclitaxel (see experiment 2 on page 15). It is not clear from these experiments how applicant came to the conclusion that the synergistic effect is from 10 to 40 fold. Also applicant refers to experiment 1 as in page 5, paragraph [0080] and experiment 2 on page 5, paragraph [0082], and there is nothing on page 5 of the specification regarding these experiments. In summary, applicant has not shown, that the claimed composition (zoledronic acid and paclitaxel) shows synergistic effects over a wide range of concentrations (except for two cases shown in experiments 1 and 2) when zoledronic acid is administered after paclitaxel, and that the synergistic effects of the two experiments shown by applicant are not much different from the ones taught by Jagdev et. al.

Withdrawn Rejections and/or Objections

Claims 1 and 5 rejected under 35 U.S.C. 102(b).

Due to applicant cancellation of claims 1 and 5, the 102(a) rejection is now moot.

Rejection under 35 U.S.C. 102(b) is withdrawn.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
December 31, 2008

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612